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January 31, 2014

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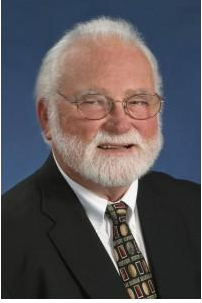
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Analysis of Subgroup Data of Clinical Trials

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A collaborative study including Dr. Kao-Tai Tsai, adjunct professor of biostatistics, and Dr. Karl E. Peace, professor of biostatistics, at the Jiann-Ping Hsu College of Public Health Georgia Southern University propose an analysis strategy of subgroup data of clinical trials. Large randomized controlled clinical trials are the gold standard to evaluate and compare the effects of treatments. It is common practice for investigators to explore and even attempt to compare treatments, beyond the first round of primary analyses, for various subsets of the study populations based on scientific or clinical interests to take advantage of the potentially rich information contained in the clinical database. Although subjects are randomized to treatment groups in clinical trials, this does not imply the same degree of randomization among sub-populations of the original trials. Therefore, comparisons of treatments in sub-populations may

not produce fair and unbiased results without properly addressing this issue. Covariate adjustments in regression analysis and propensity score matching are commonly used to address the non-randomized nature of the sub-populations issue with various degrees of success. However, further improvements to these methods are still possible.

In this article, we propose an analysis strategy that shows improvement to conventional methods. Treatment effects and their differences are estimated after adjustment for background imbalances. Treatment groups are then compared using confidence intervals whose limits are determined using the Robbins–Monro stochastic approximation. Data from a recent clinical trial are used to illustrate the methodology.